

**Notice of Allowability**

Application N .

09/702,216

Examiner

Diana B. Johannsen

Applicant(s)

GISH ET AL.

Art Unit

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 16 June 2003.
2. ☒ The allowed claim(s) is/are 32-39.
3. ☒ The drawings filed on 30 October 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- 1 ☒ Notice of References Cited (PTO-892) *(correction of prior 892)*
- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 3 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 4 ☒ Interview Summary (PTO-413), Paper No. 1103
- 5 ☐ Information Disclosure Statements (PTO-1449), Paper No. \_\_\_\_\_
- 6 ☒ Examiner's Amendment/Comment
- 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 8 ☐ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Viola T. Kung on October 30, 2003.

The application has been amended as follows:

2. **Cancel** claims 1-6 and 8-31.

3. **Amend** the claims as follows:

32. A method for determining the presence or absence of a breast cancer cell in a patient, the method comprising:

(i) detecting a nucleic acid encoding [an amino acid sequence at least 90% identical to] SEQ ID NO:2 in a sample from the patient, and

(ii) comparing expression levels of the nucleic acid in the sample from the patient to expression levels of the nucleic acid in a normal tissue sample;

wherein an increase in expression of the nucleic acid in the sample from the patient as compared to the normal tissue sample indicates the presence of a breast cancer cell in the patient.

37. The method of claim 32, wherein said detecting [step] is carried out by using a labeled nucleic acid probe.

38. The method of claim 32, wherein said detecting [step] is carried out by utilizing a biochip comprising a nucleic acid sequence encoding SEQ ID NO: 2, wherein said nucleic acid sequence is at least 90% identical to SEQ ID NO: 1.

39. The method of claim 32, wherein the nucleic acid encoding SEQ ID NO: 2 is at least 95% identical to SEQ ID NO: 1.

4. **Amend** the paragraph at page 1, after line 8, as follows:

This application [claims priority to] is a continuation-in-part of USSN [09/525,362] 09/525,361 filed March 15, 2000, a continuation-in-part of USSN [09/453,157] 09/453,137 filed December 2, 1999, now abandoned, and a continuation-in-part of USSN 09/450,810 filed November 29, 1999, now abandoned [each of which is incorporated herein by reference in its entirety].

5. **Change** the title of the application to:

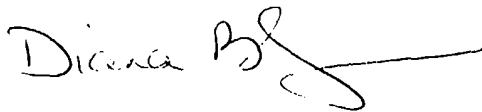
Methods of diagnosing breast cancer.

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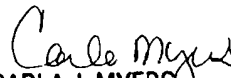
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.



Diana B. Johannsen  
November 1, 2003

  
CARLA J. MYERS  
PRIMARY EXAMINER